



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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MAY - 7 2001

WARNING LETTER
ONPLDS-15-01

Food and Drug Administration
Washington DC 20204

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Hal Katz
President
Nature's Best, Inc.
195 Engineers Road
Hauppauge, New York 11788

Dear Mr. Katz:

The Food and Drug Administration (FDA) has reviewed the label for your "PERFECT SOLID PROTEIN," 2.75 ounce bar, Chocolate Raspberry variety. We have concluded that the above product is in violation of the Federal Food, Drug, and Cosmetic Act (the Act), and Title 21, Code of Federal Regulations (21 CFR).

Your "PERFECT SOLID PROTEIN" bar is adulterated under section 402(a)(2)(C) of the Act because it contains cholecalciferol (Vitamin D₃) which is an unapproved food additive when used in this product. Cholecalciferol (Vitamin D₃) has been affirmed to be generally recognized as safe when used in accordance with 21 CFR 184.1950. Because of safety concerns raised by a cumulative dose that could result from multiple additions to foods, the regulation restricts use to the limitations specified, in accordance with 21 CFR 184.1(b)(2).

The product is misbranded under section 403(i)(1) of the Act because "PERFECT SOLID PROTEIN" is not an appropriate statement of identity. The statement of identity must be in terms of a common or usual name, or in the absence of a common or usual name an appropriately descriptive term, e.g., meal replacement bar.

The product is also misbranded under section 403(a)(1) of the Act because the label bears the statement "Glycerine is not a Carbohydrate but has a caloric value of 4.32 per gram." Glycerine is a carbohydrate. In addition, it is not clear whether glycerine is included in your declaration of "total carbohydrates" for this food. Glycerine must be included in the value declared for "total carbohydrates."

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The product is further misbranded under section 403(r)(1)(A) of the Act because the label bears the claim "high protein," but fails to declare in the nutrition information the amount of protein per serving expressed as a percentage of the Daily Value (DV) [21 CFR 101.9(c)(7)(i)].

The above violations are not meant to be an all-inclusive list of deficiencies on your label. It is your responsibility to ensure that all of your products are labeled in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct these deviations and prevent their recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. Copies of the revised label should also be submitted. If corrective actions cannot be completed within 15 working days, state the reason for delay and the time within which corrections will be completed.

You should direct your written reply to me at the Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810), 200 C Street, S.W., Washington, D.C. 20204.

Sincerely yours,

/s/

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition